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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,199	06/23/2001	David O'Leary	NHC0031A-USA	8435

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IVAX Corporation
4400 Biscayne Boulevard
Miami, FL 33137

EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,199

Applicant(s)

O'LEARY, DAVID

Examiner

Nihir Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative. The term "A new and improved" should not be disclosed in the abstract.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 through 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 1, there is insufficient antecedent basis for

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limitations “the dispensing port”, “the sealed reservoir”, “the pressure relief port”, “the channel”, and “the recess”.

Referring to claims 2 and 7, there is insufficient antecedent basis for limitations “the cup assembly” and “the reservoir”.

Referring to claim 3, there is insufficient antecedent basis for limitations “the reservoir” and “the pressure relief port”.

Referring to claim 4, there is insufficient antecedent basis for limitations “the cup assembly”, “the channel”, “the cup”, and “the recess”.

Referring to claim 5, there is insufficient antecedent basis for limitations “the sled”, “the pressure relief port”, and “the dispenser port”.

Referring to claim 6, there is insufficient antecedent basis for limitations “the cup assembly”, “the cup”, “the cup sled”, and “the reservoir”.

Referring to claim 8, there is insufficient antecedent basis for limitations “the cup assembly”, “the channel”, and “the yoke”.

Referring to claim 9, there is insufficient antecedent basis for limitations “the cup spring biasing the cup assembly”, “the recess”, “the dispensing port”, and “the reservoir”.

Referring to claim 10, there is insufficient antecedent basis for limitations “the yoke”, “the recess”, “the cup assembly”, and “the dispensing port”.

Referring to claim 11, there is insufficient antecedent basis for limitations “the yoke” and “the cam”.

Referring to claim 12, there is insufficient antecedent basis for limitations “the cam”, “the yoke”, “the recess”, “the dispensing port”, and “the cup assembly”.

Referring to claim 13, there is insufficient antecedent basis for limitations “the reservoir”, “the yoke”, and “the bellows”.

Referring to claim 14, there is insufficient antecedent basis for limitations “the mouthpiece”, “the cover”, and “the yoke”.

Referring to claim 15, there is insufficient antecedent basis for limitations “the cam”.

Referring to claim 16, there is insufficient antecedent basis for limitations “the reservoir”.

Referring to claim 17, “the recess”, “the cup assembly”, “the dispensing port”, “the bobbin”, “the ribbon”, “the spool”, and “the pawl”.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 through 7, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaeffer et al. U.S. Patent No. 6,065,471. Referring to claim 1, Schaeffer discloses an inhalation device that comprises a sealed reservoir (6) including a dispensing port (13) (Refer to figures 1, 3, column 3 lines 15 through 20, and column 4 lines 15 through 20; a channel communicating with the dispensing port and including a pressure relief port (Refer to figures 3 and 4, and column 4 lines 15 through 25); a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel (Refer to figures 3 and 4 and column 4 lines 15 through 25); a cup assembly movably received in the channel and including a recess (22) adapted to receive medicament when aligned with the

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dispensing port, a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and a second sealing surface adapted to sealing the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port (Refer to figures 1 through 9 and column 4 lines 40 through 65).

Referring to claim 2, Schaeffer shows that the cup assembly includes a sealed spring (25) biased the first sealing surface against the reservoir (Refer to figure 7 and column 4 lines 50 through 55).

Referring to claim 4, Schaeffer shows that the cup assembly includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface and the sled defining the second sealing surface (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 5, Schaeffer shows that the sled defines an indentation adapted to align with and unseal the pressure relief port when the first sealing surface is aligned with the dispenser port (Refer to figure 10 and column 5 lines 1 through 10).

Referring to claim 6, Schaeffer shows a cup assembly that includes a sealing spring (25) between the cup and the cup sled, biasing the first sealing surface of the cup against the reservoir (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 7, Schaeffer shows that the channel extends linearly and the cup assembly is movable in opposing directions within the channel (Refer to figures 1 and 7 and column 4 lines 40 through 65).

Referring to claim 9, Schaeffer shows that the cup spring biases the cup assembly to a position wherein the recess is unaligned with the dispensing part of the reservoir (Refer to figures 7 and 8 and column 4 lines 40 through 65).

Referring to claim 16, Schaeffer shows that the reservoir includes a volume of dry powdered medicament (Refer to the abstract).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Whaley et al. U.S. Patent No. 6,029,661.

Schaeffer discloses the applicant's invention as claimed with the exception of providing a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed.

Whaley discloses a powder dispenser that does provide a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed. Therefore it would be obvious to modify Schaeffer's invention by providing a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed in order to provide a better flow of the medicament powder when required.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Palson et al. U.S. Patent No. 5,119,806.

Referring to claim 9, Schaeffer discloses the applicant's invention as claimed with the exception of providing a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions.

Palson discloses an inhalation device that does provide a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions. Therefore it would be obvious to modify Schaeffer's invention by providing a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 10, Schaeffer discloses the applicant's invention as claimed with the exception of providing a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions.

Palson discloses an inhalation device that does provide a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions. Therefore it would be obvious to modify Schaeffer's invention by providing a push bar that is adapted to align the recess of the cup assembly with the dispensing port upon movement

of the yoke to one of the positions in order to provide a better way to control the amount of medicament powder being delivered.

Claims 11,12,14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of MacMichael et al. U.S. Patent No. 6,405,727.

Referring to claim 11, Schaeffer discloses the applicant's invention with the exception of providing at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke.

MacMichael discloses an inhaler mechanism that does provide at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke. Therefore it would be obvious to modify Schaeffer's invention by providing at least one movable cam including at least two successive cam surfaces; and a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 12, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the

dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions.

MacMichael discloses an inhaler mechanism that does provide a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions. Therefore it would be obvious to modify Schaeffer's invention by providing a cam that includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions in order to provide a better way to control the amount of medicament powder being delivered.

Referring to claim 14, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke.

MacMichael discloses an inhaler mechanism that does provide a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke. Therefore it would be obvious to modify Schaeffer's invention by providing a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece

causes the yoke to move between the three positions of the yoke in order to prevent excessive use of the medicament powder.

Referring to claim 15, Schaeffer discloses the applicant's invention as claimed with the exception of providing a cam this is movable by rotation.

MacMichael discloses an inhaler mechanism that does provide a cam this is movable by rotation. Therefore it would be obvious to modify Schaeffer's invention by providing a cam this is movable by rotation in order to provide a better way to control the amount of medicament powder being delivered.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley et al. U.S. Patent No. 6,029,661 as applied to claim 3 above, and further in view of Palson et al. U.S. Patent No. 5,119,806.

Whaley discloses the applicant's invention with the exception of providing a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position.

Palson discloses an inhalation device that does provide a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position. Therefore it would be obvious to modify Whaley's invention by providing a yoke that is arranged to collapse the bellows when the yoke is in the first and the second position in order to provide a better way to control the amount of medicament powder being delivered.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. U.S. Patent No. 6,065,471 in view of Ashley et al. U.S. Patent No. 5,740,792.

Schaeffer discloses the applicant's invention as claimed with the exception of providing an inhaler that comprises a pawl movable along a predetermined path upon movement of the

recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose.

Ashley discloses an inhaler for powdered medications with gear-teeth counter assembly that does provide an inhaler that comprises a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose. Therefore it would be obvious to modify Schaeffer's invention by providing an inhaler that comprises a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port, and a dose counter including a bobbin, a rotatable spool, a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the ribbon, and teeth extending radially outwardly from the spool into the predetermined path of the pawl and the ribbon is advanced onto the spool during the metering of the dose so that one knows the amount of medicament powder is in the reservoir.


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Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
July 31, 2002

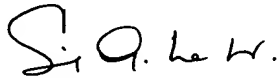

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This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands that the Examiner will make an independent evaluation of the cited publications.

No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fees to our Deposit Account No. 50-0943.

If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,



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CERTIFICATE OF MAILING (37 C.F.R. § 1.8(a))

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By:  _____